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| 09/621,146      | 07/21/2000  | Chryslain Sumian     | BJA 254A            | 3940             |

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EXAMINER

KISHORE, GOLLAMUDI S

|          |              |
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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/621,146

**Applicant(s)**

SUMIAN, CHRYSLAIN

**Examiner**

Gollamudi S. Kishore, Ph.D

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 8-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment dated 2-17-05 is acknowledged.

Claims included in the prosecution are 1-2, 5 and 8-24.

Applicant wants the examiner to address the issue as to why the prosecution was reopened in spite of previous SPE, Jose Dees' indication of allowance in a personal interview. The case was reviewed and it was determined by the SPE that the case was not in a condition for allowance and the prosecution be continued. Hence, the previous commitment of allowability was withdrawn and an office action was issued on 8-23-04

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, 5 and 8-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are three figures in the specification and in the brief description of figures 2 and 3 apparently deal with the hair follicle reaction after a swellable composition is applied. However, nowhere in the specification one can find what swellable composition is applied. In fact, with regard to

Art Unit: 1615

swellable composition, the specification only refers to some prior art and does not specifically disclose what compositions come under swellable compositions. In fact, on page 8 of the specification state, "In one preferred embodiment, the substance is a form of microsphere or liposome. As disclosed in EP 03750520 and WO 98/48716, formulations containing specific size of ingredients (e.g. microspheres or liposomes) may target compounds to follicles". First of all, according to instant claim 18, the polymers are encapsulated in liposomes whereas according to applicant's statement above refers to the 'substance *is* a form of liposomes'. This means the liposome itself is a swellable composition. These two concepts are totally different. There is no guidance provided in the specification for either of the concepts for one of ordinary skill in the art to practice the invention without undue experimentation. Secondly there is no EP patent with the number recited. Thirdly, according to the English equivalent of the WO reference cited (US 6,287,549) the microspheres are made from even fatty substances (WO is one of the references which applicant recites as a guidance for the selection of swellable composition) such as fatty alcohols and triglycerides for the preparation of microspheres (col. 2, line 63 through col. 3, line 2). These are lipophilic compounds (water repellants) and it is unclear as to how they can swell within the follicles. According to col. 3, lines 3-5 of US 6,287,549, "vesicular microparticles may also be used as liposomes and, preferably, polymerized liposomes whether reverse or forward". This statement clearly implies that liposomes themselves are microparticles and not that the polymers are within the liposomes. In essence, instant specification does not provide adequate guidance to one of ordinary skill in the art as to which swellable

Art Unit: 1615

compounds come under the definition of swellable compositions or how to use liposomes in practicing the invention without undue experimentation.

Applicant's arguments have been fully considered, but are not found to be persuasive. The only response by applicant is that " In reply to the more general 112 and 102 objections, the reply begins with a restatement of the novel aspects of the invention and as reflected in amended claims<sup>1</sup>, new claims 21-4, and previously presented claims". Since no specific arguments have been presented for the issues raised by the examiner, this rejection is maintained and extended to the added claims.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10, 11, 12, 16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'photosensitizer molecules, their derivatives and their precursors used in photodynamic therapy' as recited in claim 11. If the derivatives and precursors have photosensitizing property, then they also come under the category of 'photosensitizer molecules'. The examiner suggests the deletion of ', their derivatives and their precursors'.

This rejection is maintained since contrary to the indication, the term, 'derivatives' is still in the claim.

Claim 12 specifies that the swellable composition of claim 1 to be cosmetically/pharmaceutically acceptable. Does this mean that the composition of claim 1 includes even cosmetically/pharmaceutically non-acceptable compositions?

This rejection is maintained since contrary to the indication, this claim is not canceled.

It is unclear as to what applicant intends to convey by 'polymers are encapsulated' in claim 16. Does applicant mean that the polymers are in the form of microspheres? That is what is conveyed in the specification. Similar is the case with 'polymers are encapsulated in liposomes' as recited in the specification. There is inadequate description of this expression in the specification.

This rejection is maintained since applicants have not addressed this issue adequately.

It is unclear what applicant intends to convey by "swelling composition is covered during said volume swelling, and whereby horizontal swelling of said swelling composition is favored against vertical swelling. Is the skin area is covered or swelling composition is covered? Secondly, a hair follicle is three-dimensional and when a swelling composition is applied, naturally it will penetrate the follicle and swell both horizontally and vertically filling up the interior of the follicle. The terminology is confusing.

Upon consideration, the double patenting rejection is withdrawn.

In view of applicant's amendment, the 102 rejections are withdrawn.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549) cited above.

WO teaches a method wherein a swellable polymeric particle or polymeric liposomal composition containing chromophores (phthalocyanins) is applied onto the skin. Since the composition in WO is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; since the same polymers are used they would swell the same way in instant method and the method in the prior art (see abstract, col. 2, line 45 through col. 3, line 50, col. 5, lines 62-67 and claims). What is lacking in WO is the teaching of the removal of hair before application of the swellable composition. However, since the purpose of the method is to make the active agent in the composition to penetrate the follicles, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition. WO does not provide specific examples showing the method using the liposomes (there are no examples in instant specification

Art Unit: 1615

either). However, in view of the guidance provided by WO, it is deemed obvious to one of ordinary skill in the art to use liposomes with a reasonable expectation of success.

7. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above.

Schaefer teaches a method wherein a swellable polymeric particle composition containing various active agents is applied onto the skin for selective entry into follicles. The composition is applied to the skin with a gentle massage. Since the composition in Schaefer is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; since the same polymers are used they would swell the same way in instant method and the method in the prior art (see abstract, col. 2, line 5 through col. 4, line 54, col. 5, line 1 through col. 8, line 35, Examples and claims). What is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. However, since the purpose of the method is to make the active agent in the composition to penetrate the follicles, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition.

8. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549) cited above, further in view of Li (5,914,126) and/or Nakamura, 1980.

The teachings of WO have been discussed above. As pointed out above, what is lacking in WO is the teaching of the removal of hair before application of the swellable composition. What is also lacking in WO is the



Art Unit: 1615

teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Nakamura while disclosing the anti-inflammatory activity of a topical glucocorticoid, fludroxycortide teaches that the depilation of the backs of the rats and then applying the tape containing fludroxycortide (abstract).

Preshaving of the skin or removing the hair and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li and also from Nakamura. One of ordinary skill in the art would be motivated further to use liposomes, since liposomes are sustained release compositions and have been used in the art for the delivery of active agents as evident from Li.

Applicant's arguments have been fully considered, but are not persuasive.

Applicant argues that the present invention is not a hair removal method and that Li et al deals with delivering materials into a hair follicle to be able to treat/kill the remnant follicle structure. This argument is not found to be persuasive since instant claim language does not exclude the subsequent permanent hair removal.

9. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above, further in view of Li (5,914,126) and/or Nakamura(1980).

Art Unit: 1615

The teachings of Schaefer have been discussed above. As pointed out above, what is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. What is also lacking in Schaefer is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Nakamura while disclosing the anti-inflammatory activity of a topical glucocorticoid, fludroxycortide teaches that the depilation of the backs of the rats and then applying the tape containing fludroxycortide (abstract).

Preshaving of the skin and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li and Nakamura.

Applicant provides no specific arguments regarding this rejection. The rejection is maintained.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1615

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK